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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,469	11/03/2001	David W. Buck	17810-510 NATL	3254

7590 09/16/2003

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EXAMINER
HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,469	BUCK ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-51* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-20, 22 & 24-26, drawn to a method of producing a population of enriched CNS stem cells, classified in Class 435, subclass 368.

   II. Claim 21, drawn to methods for identifying a neurosphere initiating stem cell, classified in Class 435, subclass 7.21.

   III. Claims 23 & 27-39, drawn to a population of neurosphere initiating stem cells, classified in Class 435, subclass 325.

   IV. Claims 40-41, drawn to a method of characterizing a neurosphere initiating stem cell through differentiating culture conditions, classified in Class 435, subclass 377.

   V. Claims 42-43 & 45-47, drawn to a method of detecting the presence of a growth factor that affects the growth of a neurosphere, classified in Class 435, subclass 336.

   VI. Claims 44 & 48-51, drawn to cell therapy methods involving transplantation of neurospheres, classified in Class 424, subclass 93.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions III and I-II, VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the *in vitro* cell cultures of Group III can be used in materially different diagnostic methods to assay expression of different neuronal-specific proteins, or as sources to produce neuronal-related proteins or gene transcripts. In contrast, the method of enriching of Group I or the method of identifying neuronal stem cell cultures of Group II require antibodies and/or detection protocols not required in the products of Group III. In addition, the method of Group VI requires patients and administration protocols not required for Group III. These inventions are, therefore, patentably distinct, since one is not required for the other.

Although there are no provisions under the section for "Relation of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed proper because these methods appear to constitute patently distinct inventions for the following reason:

Groups I-II & IV-VI are directed to methods of producing a population of enriched CNS stem cells (Group I), identifying a neurosphere initiating stem cell (Group II), a method of characterizing a neurosphere initiating stem cell through differentiation (Group IV), a method of detecting the presence of a growth factor that affects the growth of a neurosphere (Group V), or methods involving cell therapy (Group VI). Each of these methods require physically and

functionally distinct elements, and possess different method steps and goals. For example, the methods of Group I-II & V-VI are distinct from the method of Group IV because the method of Group IV requires differentiation conditions not required in the methods of Groups I-II & V-VI, and vice versa. The detection methods of Groups II and V are distinguished because they require contacting neural stem cells with reagents and detection protocols not required in the methods of Groups I, IV and VI, and vice versa. The method of Groups II is distinguished from the method of Group V in that neurosphere determinants are required to be contacted and detected, versus the detection of growth factors required in the method of Group V, and vice versa. The methods of Groups I & VI are distinguished from the method of Group IV in that the method of Group IV requires detection of neurons, oligo-dendrocytes or astrocytes, which are not required in the proliferation method of Group I, or the transplantation method of Group VI, and vice versa. The method of Group V requires detection of growth factors, which is not required in the methods of Groups I, II, IV or VI, and vice versa. Lastly, the methods of Group VI require patients and administration protocols not required in the methods of Groups I, II, IV or V, and vice versa. These inventions are, therefore, patentably distinct, since one is not required for the other.

Because these inventions are distinct for the reasons given above, they have acquired a separate status in the art as shown by their different classification, and the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and consider all the separable groups with their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert C. Hayes, Ph.D.
September 15, 2003